IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(NORTHERN DIVISION)

ROBERT WITT, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	No. 1:20-CV-01249

DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S ANSWER AND JURY DEMAND TO PLAINTIFF'S FIRST AMENDED COMPLAINT

Pursuant to Rule 12 of the Federal Rules of Civil Procedure, Defendant Novartis Pharmaceuticals Corporation ("NPC"), by and through its counsel, respectfully responds by generally denying all allegations in the First Amended Complaint and Jury Demand ("the Complaint") of plaintiff Robert Witt, except as set forth below. Silence as to any allegations shall constitute a denial:

1. The allegations in Paragraph 1 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 1 of the Complaint.

2. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint and therefore denies the same. NPC specifically denies that any injuries alleged in the Complaint were caused by Tasigna®.

3. NPC denies that any injuries alleged in the Complaint were caused by Tasigna® and denies that the plaintiff is entitled to any of the relief sought, as alleged in Paragraph 3 of the Complaint.

JURISDICTION AND VENUE

4. NPC admits that NPC is a Delaware corporation with its principle place of business located in New Jersey. The remaining allegations in Paragraph 4 constitute legal conclusions to which no response is required. To the extent that a response is deemed required, NPC denies the allegations in Paragraph 4.

5. The allegations in Paragraph 5 constitute legal conclusions to which no response is required. To the extent that a response is deemed required, NPC denies the allegations in Paragraph 5.

6. The allegations in paragraph 6 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 6.

THE PARTIES

The Plaintiff

7. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 7 of the Complaint and therefore denies the same.

The Defendant

8. NPC admits that it is a Delaware corporation with its principle place of business located in East Hanover, New Jersey. NPC admits that it researches, develops, markets, and sells the cancer medicine bearing the name Tasigna®, as well as numerous other medications. NPC denies the remaining allegations in Paragraph 8 of the Complaint.

GENERAL ALLEGATIONS

9. The allegations in paragraph 9 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 9.

10. The allegations in paragraph 10 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 10.

11. The allegations in paragraph 11 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 11.

12. The allegations in paragraph 12 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 12.

13. The allegations in paragraph 13 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 13.

14. The allegations in paragraph 14 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 14.

15. The allegations in paragraph 15 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 15.

16. The allegations in paragraph 16 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 16.

17. The allegations in paragraph 17 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 17.

18. The allegations in paragraph 18 constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 18.

19. NPC admits that Tasigna® is a cancer medication that is FDA-approved to treat patients with Philadelphia chromosome positive chronic myeloid leukemia ("Ph+CML"). NPC affirmatively avers that chronic myeloid leukemia is a cancer that occurs when the blood-forming cells of the bone marrow make too many white blood cells, including immature ones. PH+CML is caused by a genetic abnormality that produces an abnormal chromosome in bone marrow stem cells – the Philadelphia chromosome (abbreviated 'Ph chromosome" or simply "Ph"). The Ph chromosome carries a gene called BCR-ABL, which produces a protein called Bcr-Abl. The Bcr-Abl protein triggers bone marrow to keep making abnormal versions of white blood cells, which are the leukemia cells. The BCR-ABL gene and Bcr-Abl protein are the key causes of Ph+CML. The resulting uncontrolled growth of these white blood cells will cause a large increase in their concentration in the blood. Over time, these white blood cells crowd out healthy red blood cells and platelets as well as normal white cells. Tasigna® is an inhibitor of the BCR-ABL Kinase. Tasigna® is considered a tyrosine kinase inhibitor ("TKI" medicine). NPC

denies all allegations of Paragraph 19 of the complaint that are inconsistent with its affirmative averment above.

20. NPC admits that Gleevec® was first FDA approved in 2001 and that it is a drug that was and is distributed by NPC in the United States. The remaining allegations contained in Paragraph 20 of the Complaint are impertinent and immaterial as the allegations do not allege that any injuries resulted from Gleevec® treatment. Moreover, the allegations are vague in that they do not identify the payer in their hypothetical allegations regarding "cost." NPC admits that the list price of Gleevec® pills has increased in the fifteen years since market introduction in 2001 by about threefold. NPC admits that the Wholesale Acquisition Cost for twelve months of Gleevec® treatments for CML, if a patient is fully compliant, has at times been more than $100,000. NPC lacks knowledge and information regarding what Gleevec® "costs" any particular patient. NPC denies the remaining allegations contained in Paragraph 20 as they relate to NPC.

21. NPC admits that, as of July 4, 2015 the basic compound patent for Gleevec® in the United States was no longer in effect. NPC admits that there are generic versions of imatinib available. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the last clause in Paragraph 21 of the Complaint and therefore denies the same. NPC denies any remaining allegations in Paragraph 21 of the Complaint.

22. NPC admits that it was involved in the development of the cancer medicine Tasigna®. NPC affirmatively avers that, in clinical trials, Tasigna® was shown to be an effective treatment for Philadelphia chromosome-positive CML in chronic phase based on (1) an early response to treatment at 3 months; (2) a major molecular response (MMR) at 1 year; and (3) a sustained molecular response by 5 years. More patients treated with Tasigna® reached these

milestones than with Gleevec®, based on results from various clinical trials. NPC admits that the quoted language contained in Paragraph 22 has been reported, but cannot confirm the accuracy of the quotation. NPC affirmatively avers that the quotation is presented in a misleading way in Paragraph 22. NPC denies the remaining allegations in Paragraph 22 of the Complaint.

23. NPC denies the allegations in Paragraph 23 of the Complaint. Answering further, to the extent the allegations in Paragraph 23 refer to extrinsic documents not attached to or part of this Complaint, NPC states that such documents speak for themselves. NPC denies the allegations to the extent they misstate or mischaracterize such documents.

24. NPC denies the allegations in Paragraph 24 of the Complaint. Answering further, to the extent the allegations in Paragraph 24 refer to extrinsic documents not attached to or part of this Complaint, NPC states that such documents speak for themselves. NPC denies the allegations to the extent they misstate or mischaracterize such documents.

25. NPC admits that it received a letter dated July 29, 2010 from the FDA that requested that NPC remove certain content then on the Tasigna® website. NPC admits that the language contained in quotations in Paragraph 25 appears in that letter, but affirmatively avers that the quotations are presented in a misleading way in Paragraph 25. NPC otherwise denies the allegations in Paragraph 25 of the Complaint.

26. NPC denies the allegations of Paragraph 26 of the Complaint.

27. The allegations contained in Paragraph 27 relate to conduct that allegedly occurred in Japan. NPC, which does not operate in Japan, lacks knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 27 and, therefore, denies the same.

28. NPC denies the allegations contained in Paragraph 28 of the Complaint.

29. NPC admits that it identified a weak safety signal of peripheral arterial occlusive disease ("PAOD") in Tasigna® users and that NPC disclosed this to the FDA in March 2011. NPC sought and FDA approved of the addition of PAOD to Tasigna®'s US package insert in November 2011. NPC denies the remaining allegations contained in Paragraph 29 of the Complaint.

30. NPC denies the allegations in Paragraph 30 of the Complaint. Answering further, to the extent that the allegations in Paragraph 30 refer to documents not attached to or part of this Complaint, NPC states that such documents speak for themselves. NPC denies the allegations to the extent they misstate or mischaracterize such documents.

31. NPC denies the allegations contained in Paragraph 31 of the Complaint. Answering further, to the extent that the allegations in Paragraph 31 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

32. NPC denies the allegations in the first sentence of Paragraph 32 of the Complaint. NPC does not operate in Canada and, therefore, denies that these actions are attributable to NPC. Answering further, to the extent that the allegations in Paragraph 32 refer to documents not attached to or part of this Complaint, NPC states that such documents speak for themselves. NPC denies the allegations to the extent they misstate or mischaracterize such documents.

33. On April 12, 2013, Novartis Pharmaceuticals Canada, Inc., sent a letter to Canadian health care providers regarding "Updated information regarding the possible risk of developing atherosclerosis-related conditions with the use of Tasigna® (nilotinib)." NPC admits that it did not send a similar letter to health care providers in the United States on April 12, 2013. NPC denies any remaining allegations in Paragraph 33 of the Complaint. NPC does not operate

in Canada and, therefore, denies that these actions are attributable to NPC. NPC denies any allegations contained in Paragraph 33 that are inconsistent with the statements set forth in response to that paragraph above.

34. NPC denies the allegations contained in Paragraph 34 of the Complaint.

35. NPC denies the allegations contained in Paragraph 35 of the Complaint.

36. NPC denies the allegations contained in Paragraph 36 of the Complaint.

37. NPC denies the allegations in the first sentence of Paragraph 37. The remaining allegations in Paragraph 37 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is required, NPC denies the allegations.

38. NPC denies the allegations contained in Paragraph 38 of the Complaint. Answering further, to the extent that the allegations in Paragraph 38 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

39. NPC denies the allegations contained in Paragraph 39 of the Complaint. Answering further, to the extent that the allegations in Paragraph 39 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

40. NPC denies the allegations contained in Paragraph 40 of the Complaint. Answering further, to the extent that the allegations in Paragraph 40 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

41. NPC denies the allegations contained in Paragraph 41 of the Complaint.

42. NPC denies the allegations contained in Paragraph 42 of the Complaint.

43. NPC denies the allegations contained in Paragraph 43 of the Complaint. Answering further, to the extent that the allegations in Paragraph 43 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

44. NPC denies the allegations contained in Paragraph 44 of the Complaint. Answering further, to the extent that the allegations in Paragraph 44 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

45. NPC denies the allegations contained in Paragraph 45 of the Complaint. Answering further, to the extent that the allegations in Paragraph 45 refer to documents not attached to or part of this Complaint, NPC denies the allegations to the extent they misstate or mischaracterize such documents.

46. NPC denies the allegations contained in Paragraph 46 of the Complaint.

47. NPC denies the allegations contained in Paragraph 47 of the Complaint.

48. NPC denies the allegations contained in Paragraph 48 of the Complaint.

49. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 49 of the Complaint and therefore denies the same.

50. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 50 of the Complaint and therefore denies the same. NPC denies that Tasigna®'s FDA approved labeling is or was ever inadequate.

51. NPC denies the allegations contained in Paragraph 51 of the Complaint.

52. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 52 of the Complaint and therefore denies the same.

53. NPC denies the allegations contained in the last sentence of Paragraph 53 of the Complaint. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 53 of the Complaint and therefore denies the same.

54. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 54 of the Complaint and therefore denies the same.

55. NPC denies the allegations contained in Paragraph 55 of the Complaint.

56. NPC denies the allegations contained in Paragraph 56 of the Complaint.

57. NPC denies the allegations contained in Paragraph 57 of the Complaint.

58. NPC denies the allegations contained in Paragraph 58 of the Complaint. NPC specifically denies that plaintiff is entitled to punitive damages.

CLAIMS FOR RELIEF

COUNT I: PRODUCTS LIABILITY -- FAILURE TO WARN

59. In response to Paragraph 59 of the Complaint, NPC incorporates by reference its responses to the allegations in paragraphs 1-58 of the Complaint.

60. NPC admits that it is currently and between 2007 and the present was engaged in selling, marketing, promoting, and distributing Tasigna® in the United States. NPC admits that prior to 2007 it was involved in developing the cancer medicine Tasigna®. NPC denies all the remaining allegations contained in Paragraph 60 of the Complaint.

61. NPC admits that it is currently and between 2007 and the present was engaged in selling, marketing, promoting, and distributing Tasigna® in the United States. The remaining allegations in Paragraph 61 set forth conclusions of law for which no response is required. To the extent a response is required, NPC denies the allegations in Paragraph 61 of the Complaint.

62. The allegations in Paragraph 62 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 62.

63. NPC denies the allegations contained in Paragraph 63 of the Complaint.

64. NPC denies the allegations contained in Paragraph 64 of the Complaint.

65. NPC denies the allegations contained in Paragraph 65 of the Complaint.

66. NPC denies the allegations contained in Paragraph 66 of the Complaint.

67. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 67 of the Complaint and therefore denies the same.

68. NPC denies the allegations contained in Paragraph 68 of the Complaint.

69. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 69 of the Complaint and therefore denies the same.

70. NPC denies the allegations contained in Paragraph 70 of the Complaint.

71. NPC denies the allegations contained in Paragraph 71 of the Complaint.

72. NPC denies the allegations contained in Paragraph 72 of the Complaint.

73. The allegations in Paragraph 73 of the Complaint constitute legal conclusions to which no response is required. To the extent a response is deemed required, NPC denies the allegations in Paragraph 73.

74. NPC denies the allegations contained in Paragraph 74 of the Complaint.

75. NPC denies the allegations contained in Paragraph 75 of the Complaint.

76. NPC denies the allegations contained in Paragraph 76 of the Complaint.

77. NPC denies the allegations contained in Paragraph 77 of the Complaint.

78. NPC denies the allegations contained in Paragraph 78 of the Complaint.

79. NPC denies the allegations contained in Paragraph 79 of the Complaint.

In response to the WHEREFORE paragraph following paragraph 79, NPC demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that NPC be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper. NPC specifically denies that plaintiff is entitled to punitive damages.

COUNT II: NEGLIGENCE

80. In response to Paragraph 80 of the Complaint, NPC incorporates by reference its responses to the allegations in Paragraph 1-79 of the Complaint.

81. NPC admits that it is currently and between 2007 and the present was engaged in selling, marketing, promoting, and distributing Tasigna® in the United States. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 81 of the Complaint and therefore denies the same.

82. The allegations in Paragraph 82 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 82 of the Complaint.

83. The allegations in Paragraph 83 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 83 of the Complaint.

84. NPC denies the allegations contained in Paragraph 84 of the Complaint.

85. NPC denies the allegations contained in Paragraph 85 of the Complaint.

86. NPC denies the allegations contained in Paragraph 86 of the Complaint.

87. The allegations in Paragraph 87 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 87 of the Complaint.

88. The allegations in Paragraph 88 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in Paragraph 88 of the Complaint.

89. NPC denies the allegations contained in Paragraph 89 of the Complaint.

90. NPC denies the allegations contained in Paragraph 90 of the Complaint and each of its subparts.

91. NPC denies the allegations contained in Paragraph 91 of the Complaint.

92. NPC denies the allegations contained in Paragraph 92 of the Complaint.

93. NPC denies the allegations contained in Paragraph 93 of the Complaint.

94. NPC denies the allegations contained in Paragraph 94 of the Complaint.

95. NPC denies the allegations contained in Paragraph 95 of the Complaint.

96. NPC denies the allegations contained in Paragraph 96 of the Complaint.

97. NPC denies the allegations contained in Paragraph 97 of the Complaint.

98. NPC denies the allegations contained in Paragraph 98 of the Complaint.

In response to the WHEREFORE paragraph following paragraph 98, NPC demands that judgment be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with prejudice; and that NPC be awarded costs of suit and reasonable attorney's fees as allowed by law and such further and additional relief as this Court may deem just and proper. NPC specifically denies that plaintiff is entitled to punitive damages.

Every allegation in the Complaint that is not specifically and expressly admitted in this Answer is hereby specifically and expressly denied, including any allegations contained in the headings of Plaintiff's complaint and the prayer for relief.

AFFIRMATIVE DEFENSES

1. The Complaint, in whole or part, fails to state a claim or cause of action against NPC upon which relief can be granted.

2. Plaintiff's claims are barred by their failure to join necessary or indispensable parties.

3. The doctrines contained in Restatement (Second) of Torts § 402A, Comment K, bar plaintiff's claims against NPC in whole or in part.

4. The doctrine(s) contained in Restatement (Third) of Torts, Product Liability §§ 4 and 6, bar plaintiff's claims against NPC in whole or in part.

5. Applicable statutes of limitations or repose bar plaintiff's claims in whole or in part.

6. The equitable doctrine of laches, waiver and/or estoppel bar plaintiff's claims in whole or in part.

7. Plaintiff's misuse or abnormal use of the products or failure to follow instructions bar the plaintiff's claims in whole or in part.

8. The alleged injuries to plaintiff were proximately caused by the misuse, abuse, alteration, and/or failure to properly utilize, maintain, or care for the products by persons other than NPC.

9. Plaintiff's claims are barred, in whole or in part, because the plaintiff assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.

10. Any alleged negligent or culpable conduct of NPC, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiff's alleged injuries.

11. To the extent plaintiff used the product for "off-label" purposes, plaintiff's claims are barred.

12. The "learned intermediary" doctrine bars plaintiff's claims.

13. Plaintiff's claims are barred, in whole or in part, because the product at issue was designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

14. Plaintiff's claims are barred, in whole or in part, because the labels and information accompanying the products at issue were approved by the U.S. Food and Drug Administration or other appropriate regulatory agencies.

15. Plaintiff's claims are barred, in whole or in part, by applicable products liability statutes or other law providing absolute or limited immunity or a disputable presumption of immunity against liability for pharmaceutical products approved by the FDA.

16. Plaintiff's claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.

17. Plaintiff's claims are preempted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of Tasigna®.

18. Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if any, were the result of conduct of plaintiff, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to plaintiff's pre-existing medical conditions.

19. If plaintiff suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which NPC is neither liable nor responsible or resulted from diseases and/or causes that are not related to or connected with any product sold, distributed, or manufactured by NPC. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of plaintiff's alleged injury or damages.

20. Plaintiff's claims are barred, in whole or in part, because plaintiff's alleged injuries, if caused by Tasigna®, which is denied, were the result of plaintiff's own idiosyncratic reactions.

21. Plaintiff failed to mitigate, which limits plaintiff's damages, if any, in whole or in part.

22. Tasigna® was fit and proper for its intended purposes and the social utility of the drugs outweighed any possible risk inherent in the use of the products.

23. NPC has no legal relationship or privity with plaintiff and owes no duty to plaintiff by which liability could be attributed to it.

24. The claims of plaintiff should be diminished in whole or in part in the amount paid to plaintiff by any party or non-party with whom plaintiff has settled or may settle.

25. Plaintiff's claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

26. Notwithstanding the claims and contentions of plaintiff, plaintiff received all or substantially all of the benefit from the products that plaintiff hoped and intended to receive, and, to that extent, any damages and/or restitution that plaintiff might be entitled to recover from NPC must be correspondingly reduced.

27. Plaintiff's causes of action are barred in whole or in part by plaintiff's own contributory/comparative negligence.

28. To the extent that the plaintiff is entitled to recover damages for medical expenses incurred prior to the conclusion of trial, such recovery is limited to the amounts paid and accepted as payment in full by any insurance benefit.

29. Plaintiff is barred from recovering any amounts that have been and/or will be covered by insurance required by and/or available pursuant to the Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 et seq. (2010) ("ACA").

30. Any damages to which the plaintiff otherwise would be entitled shall be reduced by any amount which the plaintiff has received or with reasonable certainty will receive in the future from insurance required by the ACA. This answering defendant is entitled to an offset and/or credit for any portion of the plaintiff's medical expenses payable and/or within the coverage of insurance required by the ACA.

31. Plaintiff's recovery, if any, shall be reduced by those payments that plaintiff receives from collateral sources.

32. If plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by an NPC product.

33. Plaintiff's claims for punitive and exemplary damages are barred because such an award would violate NPC's due process, equal protection and/or other rights under the United States Constitution, the Maryland Constitution, the New Jersey Constitution, and/or other applicable state constitutions.

34. Plaintiff's claims for punitive and exemplary damages are barred because plaintiff has failed to allege conduct warranting imposition of punitive damages under New Jersey law, Maryland law and/or other applicable state laws.

35. Plaintiff's claim for punitive and exemplary damages is preempted, in whole or in part, by applicable federal law and New Jersey and/or Maryland law.

36. To the extent that New Jersey law applies to plaintiff's claims, plaintiff is limited in the amount, if any, plaintiff may recover for punitive and exemplary damages under N.J.S.A. § 2A:15-5.9 *et seq*.

37. To the extent that New Jersey law applies to plaintiff's claims, plaintiff is barred from recovering punitive or exemplary damages under N.J.S.A. § 2A:58C-5(c) because Tasigna® was subject to pre-market approval by the FDA, was approved by the FDA, and/or was generally recognized as safe and effective pursuant to regulations and conditions established by the FDA.

38. Punitive and exemplary damages against NPC cannot be recovered based on alleged fraudulent representation to the FDA. *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001).

39. Plaintiff's claims for punitive and exemplary damages are barred in whole or in part because plaintiff is not entitled to compensatory damages, no fault or other admissions being made.

40. Plaintiff's claims are barred to the extent that plaintiff seeks relief under laws of states that do not govern plaintiff's claims.

41. Plaintiff's claims are barred because plaintiff's own negligence proximately caused and contributed to the injuries complained of and, therefore, the damages which might be recovered by plaintiff in this action, if any, should be reduced in proportion to the plaintiff's own negligence.

42. If plaintiffhas been injured or damaged, no injury or damages being admitted, plaintiff's claims for damages are limited by M.D. Cts. & Jud. Proc. § 11-108.

43. NPC hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves its right to amend this Answer to assert such defenses.

JURY DEMAND

Defendant Novartis Pharmaceuticals Corporation demands a jury trial as to all issues so triable.

Dated: July 16, 2020

Respectfully submitted,

s/ Robert E. Johnston
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CERTIFICATE OF SERVICE

The undersigned declares under penalty of perjury, that on the 16th day of July, 2020, I arranged for service of the foregoing Answer to the parties to this action via the Court's CM/ECF system as follows:

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